DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-51

May 8, 2000

Fernando Tapia, Vice President
Vista Mundo, Inc.
3760 N.E. 15th Terrace
Pompano Beach, Florida 33064

Dear Mr. Tapia:

This letter is in reference to your firm's marketing and distribution of your products "St. Lucia Eye Drops" and "Rectal Ointment".

Promotional literature (labeling) accompanying your products cause them to be drugs. The label for "St. Lucia Eye Drops" contains the claim "This is very useful for eye infections, stye, glaucoma, retinitis pigmentosa, cataracts and other problems of the eyes or sinusitis." The label for "Rectal Ointment" contains the claim "It is very useful for tuberculosis, candida, cancer, herpes, and infections."

Based on the above claims, these products are drugs [section 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act)] and "new drugs" [section 201(p) of the Act]. Therefore, they may not be marketed in the United States without approved New Drug Applications (NDA) [section 505(a) of the Act].

These drugs are also misbranded [section 502(f)(1) of the Act] because their labeling fails to bear adequate directions for use. The labeling is false and misleading as it suggests the products are safe and effective for their intended uses when, in fact, this has not been established [section 502(a) of the Act]. In addition, the product "Rectal Ointment" is misbranded [section 502(e)(1)(a)(ii)] because the label fails to bear the established name(s) of the active ingredients.

You have also failed to register with the FDA as a drug manufacturer and have failed to list the drug products you manufacture [section 502(o)].

Further, an inspection of your firm on February 4, 7, and 10, 2000, revealed that the drug products you manufacture are adulterated [section 501(a)(2)(B)] in that the methods used in, or the controls used for their processing, packaging or holding do not conform or are not operated or administered in conformity with the Good Manufacturing Practice (GMP) Regulations to assure that your drugs meet the requirements of the Act [21 CFR 211], as follows:

> Failure to have a quality control unit that reviews all production and testing prior to release of a batch; failure to perform any system or process validation, or any in-process, finished product, or stability testing, including microbial quality; failure to establish finished product specifications; failure to establish or maintain production records of any kind, including master production records, batch records, standard operating procedures, validation documents, and cleaning procedures or records; inadequate manufacturing facilities; and, no procedures for, or records of, consumer complaints.

This letter is not intended to be an all-inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products and for an injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not occur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be implemented.

You should reply to Martin E. Katz, Compliance Officer, U. S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751.

Sincerely,

Edward R. Atkins

Edward R. Atkins
Acting Director
Florida District